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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/020,923

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James Thacker

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EXAMINER

HINES, JANA A

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/020,923

Applicant(s)

THACKER, JAMES

Examiner

Ja-Na Hines

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-19 and 25-32 is/are pending in the application.
- 4a) Of the above claim(s) 6-10, 12-19 and 25-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 and 29-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry

1. The amendment filed December 14, 2005 has been entered. Claims 1-5, and 20-24 are cancelled. Claim 11 has been amended. Claims 33-32 have been newly added. Claims 11 and 29-32 are under consideration in this office action.

Withdrawal of Objections and Rejections

2. The following objections and rejections have been withdrawn in view of applicants' amendments and arguments:

- a) The provisional rejection of claim 11 under 35 U.S.C. 101; and
- b) The rejection of claims 11 and 29-30 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps.

Response to Arguments

3. Applicant's arguments filed December 14, 2005 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. The rejection of claims 11 and 29-32 under 35 U.S.C. 103(a) as being unpatentable over Shih et al., (US Patent 4,026,767 published May 31, 1977) in view of Harlow and Lane (1986) is maintained. The rejection was on the grounds that no more than routine skill would have been required to modify the method of detection as taught

by Shih et al., to further incorporate using specific antibodies within the colorimetric assay as taught by Harlow and Lane.

Applicants urge that the prior art method is not necessarily capable of taking less than two hours to perform. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies i.e., that the method takes less than twenty four, eight or two hours are not recited in the rejected claim 11 or 29. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants' point to the incubations period for procedures of determining the presence of a bacterium in the blood as the proof that the art teaches away from the procedure taking less than two hours. However the discovery of a previously unappreciated property of a prior art or of a scientific explanation for the prior art's functioning, does not render the old patentably new to the discoverer. *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Furthermore, there is no requirement that a person of ordinary skill in the art would have recognized that the assay could be performed in a shorter amount of time at the time of invention, rather the requirement is only that the subject matter is in fact inherent in the prior art reference. In this case, the prior art references teach the same steps using the same reagents as those instantly

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claimed, thus the fact that these same procedures can be done in a shorter amount of time, do not procedure an unexpected result, rather they simply optimize the prior art. Generally, differences in the amount of time will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such time periods are critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, applicants' assertions are not persuasive.

Applicant argues that the references teach away from the claimed invention because they disclose using a longer incubation period. However, it is the examiner's position that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). The court upheld the rejection concluding that applicant's argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since "Gurley asserted no discovery beyond what was known in the art." 27 F.3d at 554, 31 USPQ2d at 1132. Therefore contrary to applicants' argument, the prior art does not teach away from the instant claims, since the instant claims assert no discovery beyond what was known in the art.

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Applicants' urge that Harlow and Lane do not recite the teaching of formazan. However it is the examiner's position that the references failure to show a teaching of formazan is not recited in any of the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would be obvious to a person of ordinary skill in the art at the time the invention was made to modify the method taught by Shih et al., by adding additional steps to amplify the signal generated because it would help to generate more sensitive immunoassays. Furthermore, one of ordinary skill in the art would have a reasonable expectation of success because one of ordinary skill in the art would have been motivated to make such changes in method since it is well known in the art of immunoassays to use antibodies specific and sensitive within the colorimetric assays taught by Shih et al. Thus, applicants' arguments are not persuasive and the rejection is maintained.

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6. The rejection of claims 11 and 29-32 under 35 U.S.C. 112, second paragraph, is maintained for reasons of record.

a) The rejection of claim 11 was on the grounds that the preamble of the claims is drawn to a method for detecting 10,000 cfu/ml or less of microorganisms, however the recited steps within the method comprise: an incubation step; a digesting step; an incubation step; a conjugation step; and a detection step where the reporter molecule formed from the reporter-primary antibody complexes.

Applicants' assert that the amendment overcome the rejection. However the amendment states that what is being detected are reporter molecules. The reporter molecules indirectly detect the viability marker. There is no detection of the bacteria, contrary to the goal set forth by the preamble. There is no correlation that detecting the viability marker is indicative of detecting the bacteria. Thus it is suggested that detecting the bacteria is indicated by detecting the reporter-primary antibody complexes.

b) Claim 29 is unclear with respect to the method of claim 11, wherein the microorganisms comprise 1,000 cfu/mL or less. It is still unclear what microorganisms' applicant is referring too, i.e., the ones within the first incubation step or the digested microorganisms. Furthermore, it is unclear whether applicant is stating the first incubation occurs with 1,000 cfu/mL or less of microorganisms; if so it is unclear how/why one skilled in the art already knowing how many microorganisms are present would perform this method of detection. Therefore, clarification is required to overcome the rejection.

Conclusion

7. No claims allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines 
March 8, 2006


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER